

(19)



Europäisches Patentamt  
European Patent Office  
Office européen des brevets



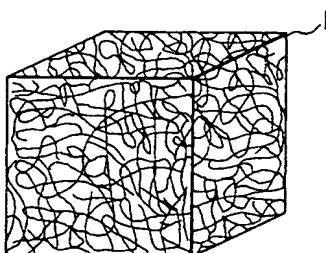
(11) Publication number:

**0 591 976 A1**

(12)

**EUROPEAN PATENT APPLICATION**(21) Application number: **93116261.4**(51) Int. Cl.<sup>5</sup>: **A61L 27/00, A61L 31/00,  
A61F 2/28**(22) Date of filing: **07.10.93**(30) Priority: **08.10.92 JP 270371/92**(43) Date of publication of application:  
**13.04.94 Bulletin 94/15**(84) Designated Contracting States:  
**DE FR GB**(71) Applicant: **KYOCERA CORPORATION**  
**5-22, Kita Inoue-cho**  
**Higashino**  
**Yamashina-ku Kyoto-shi(JP)**(72) Inventor: **Okimatsu, Hideaki, c/o Kyocera**  
**Corporation**  
**10-1, Kawai, Gamou-cho,**  
**Gamou-gun, Shiga-ken(JP)**  
Inventor: **Tamura, Yasunori, c/o Kyocera**  
**Corporation**  
**10-1, Kawai, Gamou-cho,**  
**Gamou-gun, Shiga-ken(JP)**(74) Representative: **Hiltl, Elmar, Dr. et al**  
**DIEHL.GLAESER.HILTl & PARTNER,**  
**Patentanwälte,**  
**Postfach 19 03 65**  
**D-80603 München (DE)**(54) **Porous living body repairing member, and a method of imparting elasticity to it.**

(57) A porous living body repairing member obtained by compressionmolding a metal fiber material into a desired shape, sintering the fiber mesh body, or thereafter, imparting a compressive stress of not more than 4.00 to 40.0 MPa to provide a porous living body repairing member having a compressive elasticity of not more than 2000 MPa and a permanent deformation of not more than 1 % under a stress below the compressive yield stress. When the porous living body repairing member is used at a high compressive load site such as man's lumbar body, permanent deformation hardly occurs. When said member is transplanted within the living body, its stress to the bone is well transmitted, and it acts advantageously to the bone ingrowth in the pore. At the same time, bone absorption around the repairing member is not developed.

**FIG. 1****EP 0 591 976 A1**

The present invention relates to a porous living body repairing member used in a medical treatment field, for example, orthopedic surgery, neurological surgery, oral surgery, and dental surgery, and a method of treatment for imparting elasticity thereto.

As a porous living body repairing member having a compressive elasticity close to a bone, there has been a porous living body repairing member produced by compression-molding a metallic fiber material (first compressing a metallic fiber material and accumulating it), and thereafter sintering it in vacuo as shown in the porous repairing member described in Japanese Laid Open Patent No. 109867/1988. Such a porous living body repairing member has an elasticity close to a bone, and after a certain period of time, the surface of the bone and an inner growth of the bone in the surface of the porous body immediately adjoining the bone produce a biological fixation. When it was transplanted with a bone cementing agent such as a bone cement made of polymethyl methacrylate, the intrusion of this bone cementing agent in the porous material can give a mechanical fixation with the bone.

Such a porous living body repairing member shows an improvement over the conventional living body repairing members in respect of compressive elasticity and strength. But when it is used in a highly compressive load site such as the spine and a hip joint in the living body, strain after removing a compressive stress is developed, namely permanent plastic deformation is developed.

The above-mentioned porous living body repairing member, as is generally believed, does not show elasticity under compressive load below the compressive yield stress, but actually shows a behavior near viscoelasticity. When a compressive stress above a certain limit is imparted and then eliminated, strain remains.

When the porous living body repairing member is transplanted into the living body and thereafter this deformation occurs, the biological fixation by the bones ingrowth into the porous bodies is disintegrated, with the result that "loosenings" of the living body repairing member are developed, and serious problems such as the dropping of the porous living body repairing member arise.

It is an object of this invention to provide a porous living body repairing member having almost complete elasticity under a load below the compressive yield stress in order to prevent the occurrence of permanent deformation while maintaining a compressive elasticity near a bone to solve the above problem of the conventional technique, and a method of treatment for imparting almost complete elasticity.

To solve the above problem, a metallic fiber material is compression-molded to a desired form in the present invention and a compressive stress is imparted to the shaped body to make a porous living body repairing member. The compressive yield stress of the porous living body repairing member so treated is approximately equal to the above compressive stress. Furthermore, with respect to a compressive stress of not more than the compressive yield stress, an approximately complete elasticity of a permanent deformation rate of not more than 0.1 % will be shown. Accordingly, when the porous living body repairing member is used at a high compressive load site of, for example, man's lumbar body, permanent deformation is hardly developed. Further, the magnitude of the said compressive stress may be below the maximum compressive stress which the porous repairing member of the present invention receives. When the above compressive stress is smaller, the compressive elasticity becomes smaller.

When the porous living body repairing member is adjusted to a compressive stress of not more than 40.0 MPa, its compressive elasticity can be adjusted to not more than 2100 MPa. However, when the compressive stress is lower than 4.0 MPa, its compressive yield stress becomes too small. Accordingly, then the porous living body repairing member does not become serviceable at any site in the living body.

For example, as compared with an elasticity of titanium alone or an alumina ceramic which is 110000 MPa or 390000 MPa, the porous living body repairing member of the invention has a compressive elasticity of as low as not more than 2100 MPa. It is relatively near a compressive elasticity of cancellous bone of man which is 60 to 130 MPa. When it is transplanted within the living body, stress of the bone is well transmitted. It acts advantageously for the bone ingrowth to the porous body. As seen in the living body repairing member having a high compressive elasticity, bone absorption around the living body repairing member is not developed as brought about by the shielding off of the stress.

Fig. 1 is a perspective view of the fiber mesh body illustrated in Example 1.

Fig. 2 is a graphic representation showing the relation between compression stress and strain.

Examples of the invention will be illustrated by using the drawings.

#### Example 1

A titanium fiber material having a fiber diameter of 250  $\mu\text{m}$  was knitted into a net. It was rounded and filled in a metal mold with a 15 x 15 mm square section, and press-molded at a pressure of about 150 MPa. It was sintered in vacuo at about 1300 °C to obtain an fiber mesh body having a cubic shape with a porosity

of about 50 % as shown in Fig. 1.

A compressive stress of 20 MPa and 40 MPa was imparted to fiber mesh bodies to obtain test bodies constituting porous living body repairing members.

Using these test bodies, permanent deformation rates were measured. Furthermore, compressive elasticities of these test bodies were measured. The results are shown in Table 1.

Table 1

|                     | Permanent deformation rate (%) | Compressive elasticity(MPa) |
|---------------------|--------------------------------|-----------------------------|
| Comparative Example | 0.85                           | 1473                        |
| Example 1 (20 MPa)  | 0.02                           | 1874                        |
| Example 1 (40 MPa)  | 0.02                           | 2051                        |

As Comparative Example, the cubic fiber mesh body was produced. After sintering in vacuo, the above compressive stress was not applied to form a test body of the Comparative Example. The compressive elasticity of this test body was measured and shown in Table 1.

As is clear from Table 1, the test body of the Comparative Example had a permanent deformation rate of approximately 1 %, but the test bodies according to the present invention had a permanent deformation rate of not more than 0.1 % and a compressive elasticity of 2100 MPa or below.

#### Example 2

Fiber mesh bodies 1 were produced by the method of Example 1. Compressive stresses shown in Table 2 were applied in a perpendicular direction to the mold pressurising direction to produce test bodies, and such stresses were so applied to the produced test bodies. (a) Compressive yield stress, (b) compressive elasticity under a compressive stress of not more than the above compressive yield stress and (c) permanent deformation rate (see Fig. 2) after removal of the load were measured for each test body. The results are shown in Table 2.

Table 2

| Compressive stress<br>Kgf (MPa) | Compressive yield stress/MPa | Compressive elasticity/MPa | Permanent<br>deformation rate/% |
|---------------------------------|------------------------------|----------------------------|---------------------------------|
| 100 (4.00)                      | --                           | 1256                       | 0.03                            |
| 200 (9.00)                      | 6.00                         | 1617                       | 0.03                            |
| 300 (13.00)                     | 10.00                        | 1752                       | 0.04                            |
| 400 (18.00)                     | 14.00                        | 1858                       | 0.02                            |
| 500 (22.00)                     | 17.00                        | 1825                       | 0.02                            |
| 600 (27.00)                     | 21.00                        | 1918                       | 0.00                            |
| 700 (31.00)                     | 26.00                        | 1910                       | 0.02                            |
| 800 (35.00)                     | 30.00                        | 1970                       | 0.04                            |
| 900 (49.00)                     | 33.00                        | 1972                       | 0.01                            |
| 1000 (44.00)                    | 37.00                        | 1953                       | 0.09                            |

As is clear from Table 2, the compressive yield stress is approximately equal to the compressive stress given to the fiber mesh body 1. Furthermore, after removing the load, the permanent deformation rate becomes not more than 1 %. If a compressive stress is imparted in a range of up to 40 MPa, it is possible to maintain the compressive elasticity at not more than 2100 MPa. Furthermore, when stepwise compressive loads are applied in the same direction as the mold pressurizing direction, similar results can be obtained.

The compressive stress may be applied simultaneously in the step of sintering in vacuo, but the apparatus becomes large-sized and involves a problem of facilities.

In the present invention, a metal fiber material is compression-molded into a desired shape, and compressive stress is imparted to the resulting fiber mesh body to obtain a porous living body repairing member. The compressive yield stress of the porous repairing member subjected to such a treatment is

approximately equal to the above compressive stress. Approximately complete elasticity having a permanent deformation rate of not more than 0.1 % is shown against compressive stress below this compressive yield stress. Accordingly, even when the repairing member is used at a high compressive load site such as man's lumber body, permanent deformation hardly occurs. Furthermore, by adjusting the compressive stress to not more than 40 MPa, it is possible to adjust the compressive elasticity to not more than 2000 MPa. When the repairing member is transplanted within the living body, the stress to the bone is well transmitted. It acts advantageously to the bone ingrowth within the pore, and at the same time, bone absorption around the repairing member which is brought about by the shielding off of the stress is not developed, as seen in the living body repairing material having a high elasticity.

Since the above-mentioned effect can be achieved by a simple method of imparting compressive stress, the product of the invention is clinically very effective as a living body repairing member, and contributes greatly to human welfare.

### Claims

1. A porous living body repairing member composed of a fiber mesh body obtained by compression-molding a metal fiber material into a desired shape and having a compressive elasticity of not more than 2000 MPa and a permanent deformation of not more than 0.1 % under a stress below the compressive yield stress.
2. A method of treatment for imparting elasticity to a porous living body repairing member which comprises compression-molding a metal fiber material into a desired shape, sintering the resulting fiber mesh body in vacuo, or after the end of sintering, imparting a compressive stress to the fiber mesh body with a compressive load of 4.00 to 40.0 MPa.

FIG. 1

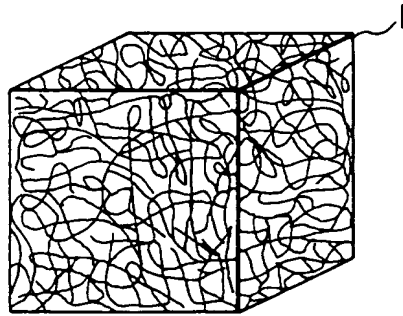
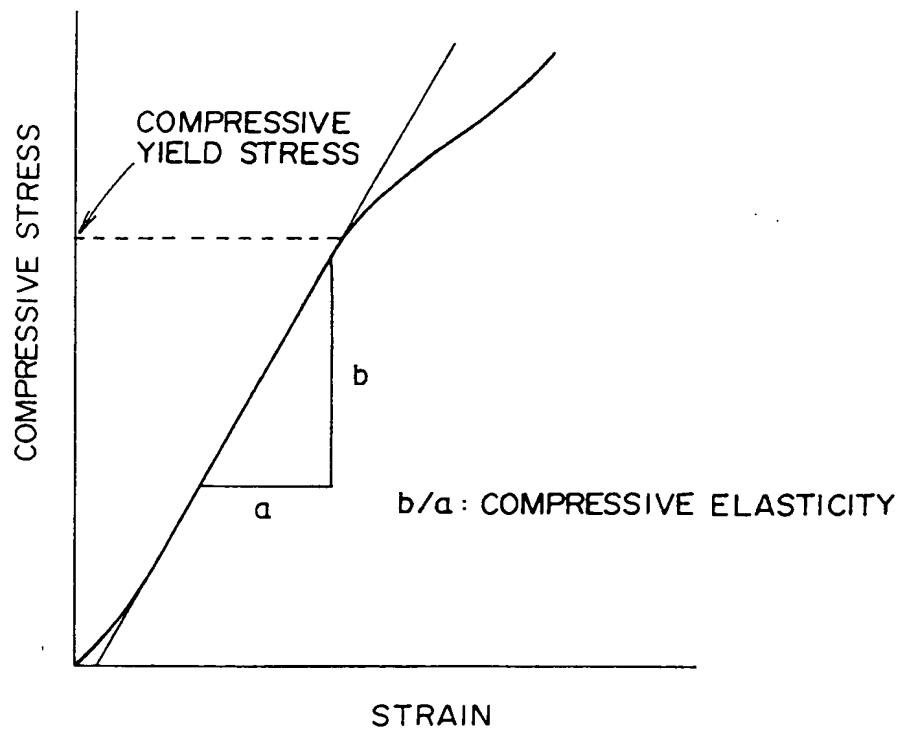


FIG. 2





European Patent  
Office

## EUROPEAN SEARCH REPORT

Application Number  
EP 93 11 6261

| DOCUMENTS CONSIDERED TO BE RELEVANT  |   |   |  |
|--|---|---|--|
| Category   | Citation of document with indication, where appropriate, of relevant passages | Relevant to claim                                   | CLASSIFICATION OF THE APPLICATION (Int.Cl.5) |
| A  | EP-A-0 225 838 (TECHMEDICA)<br>* claim 1; figure 4 *<br>---                   | 1   | A61L27/00<br>A61L31/00<br>A61F2/28           |
| A  | EP-A-0 366 018 (TECHNISCHE UNIVERSITÄT<br>KARL-MARX-STADT)<br>---             |   |  |
| P,A  | EP-A-0 526 682 (OSCOBAL)<br>-----   |   |  |
|  |   |   | TECHNICAL FIELDS<br>SEARCHED (Int.Cl.5)      |
|  |   |   | A61L<br>A61F                                 |
| The present search report has been drawn up for all claims   |   |   |  |
| Place of search<br>THE HAGUE   |   | Date of completion of the search<br>14 January 1994 | Examiner<br>PELTRE, C                        |
| <b>CATEGORY OF CITED DOCUMENTS</b><br>X : particularly relevant if taken alone<br>Y : particularly relevant if combined with another document of the same category<br>A : technological background<br>O : non-written disclosure<br>P : intermediate document<br>T : theory or principle underlying the invention<br>E : earlier patent document, but published on, or after the filing date<br>D : document cited in the application<br>L : document cited for other reasons<br>.....<br>& : member of the same patent family, corresponding document |   |   |  |